

U.S. Food and Drug Administration  
Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New  
Drug Applications and Original Biologics License Applications Under the Prescription Drug User Fee Act  
(PDUFA) and the Biologics License Applications Under the Biosimilar User Fee Act (BsUFA)

OMB Control No. 0910-0746

**CHANGE REQUEST**

**Background:**

This information collection supports Food and Drug Administration programs, specifically, evaluation of those performance goals and procedures set forth in what is known as FDA's "goals letter" or "commitment letter" under PDUFA and, more recently, BsUFA. The *goals letter* is the result of agency, industry, and public input, as Congressionally mandated under the statutes. Recently PDUFA was reauthorized, together with the Biosimilar User Fee Act of 2012. The documents entitled, "*PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*," and "*Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*" (attached), represent the renewed performance goals agreed to by FDA in support of these respective programs.

**2017-2018 Modifications:**

Consistent with the PDUFA performance goals, and currently approved under this information collection, FDA sponsors independent evaluation of the review models under which the specific product applications are submitted. FDA seeks to expand the respondent base of the information collection to include evaluations previously limited to New Molecular Entity New Drug Application (NME NDA) respondents to include respondents submitting Biologic License Applications (BLAs) under BsUFA. The purpose of the evaluation is to:

- 1) increase the efficiency and effectiveness of the first review cycle of the biosimilar application; and
- 2) decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high quality biosimilars.

The BsUFA Program evaluations mirror those of PDUFA, currently approved under this information collection, however there are fewer biosimilar actions anticipated (15 annually compared to 42 under PDUFA), and consequently fewer interviews to be conducted with sponsors of the BLAs (again, 15 interviews annually). The hourly burden associated with interviewing respondents uses a jointly agreed-upon FDA/applicant Formal Communication Plan (the same as approved for the PDUFA Program), is approximately 90 minutes or 1.5 hours (also identical to that currently approved for PDUFA), and will be conducted by an independent contractor.

**Public Outreach:**

FDA conducted two public meetings (December 18, 2015 and October 20, 2016 – see docket FDA-2015-N-3326) regarding the Biosimilar User Fee Act generally, and published a notice in the Federal Register of June 29, 2017 (82 FR 29569; docket FDA-2017-N-3199) entitled, "*Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II*" specifically discussing FDA's proposed statement of work under the BsUFA reauthorization. Comments received were supportive, and emphasized how increased and timely communications as well as feedback generated from program evaluation continues to improve and inform review models. FDA believes the proposed additional respondents would welcome the opportunity to provide us with the information we obtain from the independent evaluation authorized under this information collection, and therefore wish to include them immediately.